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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,526	07/13/2001	Sonya Merrill	ARC 2300N2	3977

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	7

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/905,526	Applicant(s) MERRILL ET AL.	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/02/03, 7/13/2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-45* is/are rejected.

7)☒ Claim(s) *13 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-45, in Paper No. 6/B is acknowledged. The traversal is on the ground(s) that oral dosage form and the extended release dosage form are not independent and they are not patentably distinct from the method of producing plasma concentrations using the dosage form. This is not found persuasive because as described in MPEP 802.01, claims are considered independent when they are unconnected in design, operation or effect. Here, oral dosage forms of Group I follow a different design, operation and pharmacokinetics effect as those of Group II. Therefore, they are considered independent.

Further, "distinct" inventions are two or more subjects that even if related, are capable of separate manufacture, use or sale as claimed and thus are patentable over each other. See MPEP 802.01. In the instant case, the extended release dosage form of Group II or methods of producing plasma concentrations of hydromorphone of Group III are respectively capable of separate manufacture, use or sale and are further patentable over each other. Thus, the subject matter of Groups II and III are considered to be independent and distinct and further capable of being patentable over each other.

Therefore, the requirement is still deemed proper and is therefore made FINAL.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re*

Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claims 1-12, 15, 19, 23-45 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-12, 13, 17, 21-43 of prior U.S. Patent No. 5,914,131. This is a double patenting rejection. The pending claims and the patented claims are directed to identical subject matter. Further, the scopes of both sets of claims are the same. Accordingly, claims are rejected under statutory double patenting-35 U.S.C 101 as they are directed to the same invention.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 13-14, 16-18, 20-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-43 of U.S. Patent No. 5,914,131.

4. Claims 1-45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7,11-14 of U.S. Patent No. 5,702,725 ('725) and claims 1-2 of U.S. Patent No. 5,529,787 ('787). Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope.

The instant claims are directed to dosage forms comprising a drug layer containing hydromorphone or salts thereof, an amount of poly(ethylene oxide), an amount of poly(vinyl pyrrolidone), and a delivery layer containing an amount of poly(ethylene oxide), an amount of sodium chloride, an amount of hydroxypropylmethylcellulose, a lubricant, an antioxidant, a colorant, and an external layer containing a passageway.

Both set of claims in '725 and '787 teach bilayer compositions comprising a drug layer containing hydromorphone, at least a polymer, and a push layer comprising poly(alkylene oxide), sodium chloride, a lubricant, an antioxidant, a colorant, and a semipermeable wall with a passageway encasing both the drug and delivery layers.

Claims of the '725 patent differ from the instant claims only in exact amounts of each ingredient. However, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the suitable amounts of each ingredient by conducting routine experimentation.

Claims of '787 patent differ from the instant claims only in the type of polymer used in their drug layer. Claims of '787 patent uses carboxymethylcellulose possessing a 100,000 to 300,000 MW. However, the instant claims employ poly(alkylene oxides)

having 200,000 MW. Nevertheless, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute these two types of polymers because they are well known functional equivalents in the art. In fact, example 8 of '787 at col 5, lines 55-59, describes that either of the polymers would provide the same end-results for the purposes of the claimed invention. Accordingly, the instant claims are obvious variants of the patented claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 18, 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18 and 22 are ambiguous because they can not properly depend on their base claims. Claim 18 depends of claim 14 which depends on claim 5. Claim 5 requires the drug layer to contain 84.70 wt% poly(ethylene oxide), 5% poly(vinylpyrrolidone), 0.05% butylated hydroxytoluene and 0.25 wt% magnesium stearate. Therefore, the maximum amount of hydromorphone that could exist in this layer can not be more than 10% wt. However, claim 18 requires this amount to be 20 wt%. Accordingly, there is a inconsistency in the amount of hydromorphone present in the drug layer and thus, the dependency of claim 18 on claim 14 is improper.

In the same manner, claim 22 depends on claim 15. Claim 15 is directed to dosage forms comprising a drug layer comprising 74.75wt% poly (ethylene oxide),

5wt% poly (vinylpyrrolidone) and 0.25wt% magnesium stearate. Accordingly, claim 15 cannot contain more than 20 wt% of the active drug within its drug layer. Claim 22, on the other hand, requires the drug layer to contain 30wt% of the active agent, hydromorphone. Therefore, the dependency of claim 22 on claim 15 is improper because it does not properly limit claim 15.

Claim Objections

6. Applicant is advised that should claim 9 and 14 be found allowable, claim 13 and 17 will be objected to under 37 CFR 1.75 as respectively being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

Shahnam Sharareh, PharmD
Patent Examiner
Art Unit 1617

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July 11, 2003